

REMARKS

I. Status of the Application.

Claims 1, 2, 4-12, 16, 17 and 43-47 were pending in the above-referenced Application. In the Office Action, the Examiner rejected all of the pending claims under 35 U.S.C. § 103(a) as being allegedly unpatentable over U.S. Patent No. 6,062,224 to Kissinger et al. ("Kissinger") in view of U.S. Patent No. 5,609,572 to Lang ("Lang") or U.S. Patent No. 5,037,390 to Raines et al. ("Raines"). Applicants respectfully submit that the foregoing amendments to the claims and the following remarks incorporated herein overcome the rejections to the aforementioned claims.

II. Applicants' Amendments Do Not Constitute New Matter.

Applicants respectfully submit that the amendments to the claims are supported by the Application as originally filed in the Figures, the specification, and originally filed claims. For these reasons, Applicants respectfully submit that amended claims are supported by the specification as originally filed and that no new matter has been submitted by way of amendment. Accordingly, Applicants respectfully request that these amendments be entered.

III. The Rejection of Claims 1, 2, 4-12, 16, 17 and 43-47 Under 35 U.S.C. § 103(a) Should Be Withdrawn.

Applicants respectfully submit that the rejection of claims 1, 2, 4-13, 16, 17, and 43-47 should be withdrawn because the Examiner fails to establish a *prima facie* case of obviousness in the Office Action. Specifically, Applicants respectfully submit that the combination of the cited

references do not disclose all the elements of the claims in order to support a conclusion of obviousness.

A) The Rejections of Claims 12 and 45 Under 35 U.S.C. §103(a) Should Be Withdrawn.

The Examiner rejected claims 12 and 45 as being obvious over Kissinger in view of Lang or Raines. In response, Applicants have cancelled claims 12 and 45. Accordingly, Applicants respectfully submit that the rejection of claims 12 and 45 are moot and Applicants respectfully request that the rejections of claims 12 and 45 under 35 U.S.C. §103(a) should be withdrawn.

B) The Rejections of Claims 1, 2, 4-11, 16, 17, 43, 44, and 46-47 Under 35 U.S.C. §103(a) Should Be Withdrawn Because a *Prima Facie* Case For Obviousness Has Not Been Established.

Applicants respectfully submit that the Examiner failed to establish a *prima facie* case for obviousness for the amended claims 1, 2, 4-11, 16, 17, 43, 44, and 46-47 because the cited references, alone or in combination, do not disclose all the limitations of Applicants' claims. As stated in the Manual of Patent Examination and Procedures ("MPEP"), "[t]he examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. MPEP §2141 (8th Ed., Rev. 6) (2007). If the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness." *Id.* at §2141. The Examiner needs to step in the "shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made" and determine "whether the claimed invention "as a whole" would have been obvious at that time to that person." *Id.* (emphasis added). In making such a determination, the Examiner must avoid use of impermissible hindsight

and "the legal conclusion must be reached on the basis of the facts gleaned from the prior art." *Id.* (emphasis added). After performing such an analysis, the Examiner then must articulate the findings of fact concerning the state of the art and the teachings of the references applied, and should provide an explicit analysis supporting the obviousness rejection under 35 U.S.C. § 103(a) to properly establish a *prima facie* case of obviousness. *Id.*; *See also, KSR Int'l. Co. v. Teleflex, Inc.*, 550 U.S. ___, 127 S.Ct. 1727, 1740-41 (2007).

Applicants respectfully submit that the rejections of claims 1, 2, 4-11, 16, 17, 43, 44, and 46-47 under 35 U.S.C. §103(a) over Kissinger in view of Lang or in view of Rains should be withdrawn because none of the cited references disclose a drug delivery device that comprise syringes that are each connected to an independent reservoir by a disposable plastic tube(s), pinch valves that are not in communication with the fluid passing through the tubes, and a controller or electronic circuitry that controls the syringes and valves to deliver fluid or flush the device, as claimed in claims 1 and 43. "In determining the differences between the prior art and the claims, the question under 35 U.S.C. 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious." *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530 (Fed. Cir. 1983) (emphasis own); MPEP § 2141.02. Applicants respectfully submit that due to the various differences between the claimed device and the prior art, taken as a whole, the claimed device is not obvious.

Several differences exist between the combination of Kissinger and Lang and the device of amended claims 1 and 43. Kissinger discloses a system for conducting biomedical tests on a

freely-moving animal. The focus of the Kissinger system is to sample bodily fluids from an animal without restricting the animal's movement. In conducting the biomedical tests – namely withdrawing blood samples from the animal – the system in Kissinger uses tubing that continuously extends from a saline reservoir to the subject animal. (Col. 21, ll. 9-16). To control the fluid flowing through the tubing, Kissinger uses pinch valves to open and close the tubing, "which do not physically contact the blood [collected from the animal]." (Col. 21, ll. 44-47; Col. 24, ll. 21-23). Kissinger uses these pinch valves in order to prevent residue (e.g., clotted blood), from building within the valves. (Col. 24, ll. 21-23).

To the Kissinger disclosure, Lang adds the medicament administration apparatus and infusion system for delivery of multiple drugs to a subject. In essence, Lang adds a drug delivery device to the blood sampling system disclosed by Kissinger. Lang uses a combination of cassettes for connection to infusion lines, inlet valves, liquid distribution ducts, pump chambers, outlet valves, and venting filters and chambers. One of the cassettes in particular, the "medicament administration cassette E," comprises five disposable plastic syringes that serve as medicament containers. (Col. 9, ll. 27-35). These five disposable plastic syringes are all connected "with the inlet connector 110 and the outlet connector 109 and furthermore with each other with the aid of ducts." (Col. 9, ll. 18-27; Figures 8-9). Infusion solution may be added from a single reservoir into the inlet connector 110, which is in fluid communication with all of the syringes of the system. (Col. 10, l. 60 – Col. 11, l. 5). In contrast, the syringes in claims 1 and 43 are connected to their own independent reservoirs.

Further, the multiple infusion containers of Lang do not supply the syringes of Lang with infusion solution, and instead feed into a single pump chamber that facilitates the advancement of the fluids from the multiple reservoirs into the patient's vein. (Col. 5, l. 60 – Col. 6, l. 8; Col. 6, l. 50 – Col. 7, l. 15; Figures 8-9). "[T]he pump chamber[] may be evacuated by a plunger advanced by an electric stepper motor in accordance with a program." (Col. 9, ll. 4-12). Accordingly, during the operation of the system of Lang, and as shown in detail in the figures (in particular, Figure 3), the pump chamber coupled with the multiple reservoirs of Lang is of the type that is filled with the fluid from the reservoirs. Further, this "filling is performed in alternating succession from the five infusion containers." (Col. 7, ll. 52-54). Lang utilizes pneumatic vales to control the flow of fluid into the pump chamber and these pneumatic valves are in fluid communication with the fluid flowing through the lines of the tubing of the system. As such, residues of the different fluids fed into the pump chamber remain within the pump chamber and the pneumatic valves even after the fluid is pumped therethrough. In contrast to the combination of Kissinger and Lang, the devices of claims 1 and 43 comprise syringes that are each connected to an independent reservoir by a disposable plastic tube(s), pinch valves that are not in communication with the fluid passing through the tubes, and a controller or electronic circuitry that controls the syringes and valves to deliver fluid or flush the device.

Likewise, Raines adds to Kissinger a closed system for mixing active ingredients that will be later administered to a patient. In essence, Raines also adds a drug delivery device to the blood sampling system of Kissinger. The Raines apparatus comprises a plurality of vials

containing additives, where each of the vials is coupled with a syringe via a two-way valve mounted on a manifold. The desired additives are withdrawn from the vials by manipulation of the syringe(s), passed through the valve(s), and allowed to flow into the manifold, through a tube, and into a final container. (Col. 5, ll. 47-62). Further, the vials, manifold, and syringes of the Raines apparatus are placed "for sterile laminar airflow under the hood of [a] sterile environment containment device." (Col. 6, l. 65 – Col. 7, l. 1). Accordingly, the valves of Raines are in fluid connection with the additives flowing therethrough. (See Figures; Col. 5, ll. 47-62) In contrast to the combination of Kissinger and Raines, the devices of claims 1 and 43 comprise syringes that are each connected to an independent reservoirs by a disposable plastic tube(s), pinch valves that are not in communication with the fluid passing through the tubes, and a controller or electronic circuitry that controls the syringes and valves to deliver fluid or flush the device.

Applicants respectfully submit that as discussed above, neither Kissinger, Lang, nor Raines, alone or in combination, disclose all the limitation of claims 1 and 43. While the Examiner combines two drug delivery systems (Lang and Rains) with a blood sampling system (Kissinger) and concludes that all the elements of claims 1 and 43 are disclosed, the Examiner fails to note that neither Kissinger in combination with Lang or Kissinger in combination with Raines discloses a drug delivery device comprising each syringe connected to an independent reservoirs by disposable plastic tubes, pinch valves that are not in communication with the fluid passing through the tubes, and a controller or electronic circuitry that controls the syringes and

valves to deliver fluid or flush the device, as claimed in claims 1 and 43. As discussed above, both Raines and Lang are the drug delivery devices and merely adding them to the blood sampling system of Kissinger does not change the fact that neither the drug delivery devices of Raines and Lang disclose the use of pinch valves that are not "in communication with the fluid", as claimed in claims 1 and 43. Rather both the devices disclosed in Raines and Lang have valves that are in communication with the fluid.

Thus, for the Examiner to successfully state its case for obviousness, it is respectfully submitted that the Examiner needs to provide an explicit analysis as to why it would be obvious to one of ordinary skill in the art to modify Raines or Lang (or some other drug delivery device) to include all the claimed limitations of independent claims 1 and 43, because the combination of Kissinger with Lang or Raines does not disclose a drug delivery system that comprises pinch valves that are not "in communication with the fluid." Rather, the combination of both Lang and Kissinger and Raines and Kissinger disclose a combination of blood sampling system and a drug delivery device, wherein the drug delivery device contains valves that are in fluid communication with the fluid that passes therethrough. For these reasons, Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness and the rejections of independent claims 1 and 43 should be withdrawn.

C) The Rejections of Claims 2, 4-11, 16, 17, 44, and 46-47 Should Also be Withdrawn.

Applicants also respectfully submit that the rejections of claims 2, 4-11, 16, 17, 44, and 46-47 under 35 U.S.C. §103(a) should also be withdrawn because each of these claims depend

from and incorporate all the limitations of either independent claim 1 or 43. MPEP §2143.03 (citing *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988) (if an independent claim is nonobvious under 35 U.S.C 103, then any claim depending therefrom is nonobvious)). For these reasons, the Applicants respectfully submit that the rejection of amended claims 1, 2, 4-11, 16, 17 and 43, 44, 46, and 47 under 35 U.S.C. § 103(a) as being obvious over Kissinger in view of Lang or Raines should be withdrawn and the pending claims should proceed to allowance.

IV. Applicants Petition for an Extension of Time.

Applicants hereby petition for an extension of time of three (3) months, under 37 C.F.R. § 1.136(a), thereby extending the deadline for response, pursuant to 37 C.F.R. §§ 1.7(a) & 1.136(a), to Friday, February 22, 2008. Applicants authorize payment for this extension in the amount of \$525.00 to be charged to the identified credit card. When doing so, please reference the above-listed docket number for this file.

V. Request for Continued Examination.

In response to the August 22, 2007 Office Action, Applicants make a Request for Continued Examination under 37 C.F.R. §1.114. Applicants enclose a Request for Continued Examination Transmittal Form PTO/SB/30 (11-07) and authorize payment for this extension in the amount of \$405.00 to be charged to the identified credit card. When doing so, please reference the above-listed docket number for this file.

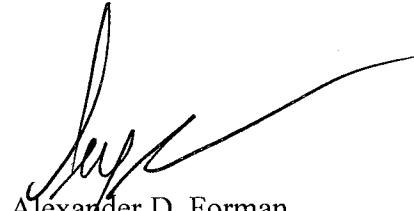
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CONCLUSION

For the foregoing reasons, it is respectfully submitted that claims 1, 2, 4-11, 16, 17 and 43, 44, 46 and 47 are allowable claims. Allowance of this Application is therefore respectfully requested. Applicants electronically submit herewith payment in the amount of \$930.00, \$405.00 of which is for the request for continued examination and \$525.00 of which is for a three (3) month extension of time by a small entity. In the event Applicants have inadvertently overlooked the need for payment of any additional fees, Applicants conditionally petition therefore and authorize any deficiency to be charged to deposit account 09-0007. When doing so, please reference the above-listed docket number. If there are any further objections or rejections, the Examiner is invited to contact the undersigned to discuss the Application.

Respectfully submitted,

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